

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA ex rel.
RONDA OSINEK,

Plaintiff,

v.

PERMANENTE MEDICAL GROUP, INC,
et al.,

Defendants.

Case No. [13-cv-03891-EMC](#)

CONSOLIDATED MEMBER CASES

Case No. [16-cv-01558-EMC](#)

Case No. [16-cv-05337-EMC](#)

Case No. [18-cv-01347-EMC](#)

Case No. [21-cv-03124-EMC](#)

Case No. [21-cv-03894-EMC](#)

**ORDER GRANTING IN PART AND
DENYING IN PART DEFENDANTS'
MOTION TO DISMISS UNITED
STATES' COMPLAINT IN
INTERVENTION**

Docket No. 178

The above-referenced case consists of several consolidated cases that charge Kaiser entities with making false claims for payment to the federal government. The main claims asserted against the Kaiser entities are violations of the federal False Claims Act (“FCA”). Following the Court’s order of May 5, 2022, *see* Docket No. 171 (order), the following cases remain:

- (1) The United States’ complaint in intervention (Docket No. 110);
- (2) The first amended complaint in *Osinek* (Docket No. 87);
- (3) Parts of the second amended complaint in *Taylor* (Docket No. 118); and
- (4) Parts of the first amended complaint in *Bryant* (Docket No. 117).¹

¹ The Court’s order also dismissed the claims in *Bicocca* except to the extent the first amended complaint (Docket No. 16 in Case No. C-21-3124 EMC) pled claims under the California False

1 Currently pending before the Court are four motions to dismiss filed by the relevant Kaiser
2 entities. The motions are targeted at all of the cases that remain. This order addresses only the
3 motion to dismiss the United States' complaint in intervention. Having considered the parties'
4 briefs, the Court hereby **GRANTS** in part and **DENIES** in part the motion to dismiss.

5 **I. FACTUAL & PROCEDURAL BACKGROUND**

6 In its complaint, the United States alleges as follows.

7 "Medicare is a federally operated health insurance program." U.S. Compl. ¶ 52. It has
8 four parts:

- 9 • Part A, which covers inpatient and institutional care.
- 10 • Part B, which covers outpatient care.
- 11 • Part C, which is the Medicare Advantage program at issue in this case.
- 12 • Part D, which covers prescription drugs.

13 *See* U.S. Compl. ¶ 52.

14 Parts A and B are "traditional" Medicare.

15 [T]he Government reimburses healthcare providers using a fee-for-
16 service system, in which providers submit claims to CMS [Centers
17 for Medicare and Medicaid Services] for healthcare services actually
18 rendered, such as a provider office visit or hospital stay. CMS then
pays the providers directly for each service based on payment rates
predetermined by the Government.

19 U.S. Compl. ¶ 53.

20 A Medicare beneficiary can opt out of traditional Medicare and enroll instead in a
21 Medicare Advantage plan ("MA plan") managed by a Medicare Advantage organization ("MA
22 organization" or "MAO"). *See* U.S. Compl. ¶ 54. "CMS reimburses MA plans differently than
23 traditional Medicare." U.S. Compl. ¶ 57. Specifically, Medicare Advantage uses a "capitation"
24 payment system." *United States ex rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667, 672 (9th Cir.
25 2018). Under that system, "private health insurance organizations provide Medicare benefits in

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27 Claims Act. *See* Docket No. 171 (Order at 46). However, prior to the Court's order, the plaintiff
28 in *Bicocca* had dismissed those state law claims. *See* Docket No. 159 (notice of voluntary partial
dismissal with respect to Counts III and IV of FAC). Accordingly, there is nothing left in
Bicocca.

1 exchange for a fixed monthly fee per person enrolled in the program – regardless of actual
2 healthcare usage.” *Id.* The fixed monthly fee for an enrollee is set as follows. First, there is a
3 predetermined base payment for each enrollee in a Medicare Advantage plan. *See* U.S. Compl. ¶
4 57. Second, the base payment is then adjusted “to account for (1) demographic factors such as age
5 and gender (among others) and (2) health status. This is known as risk adjustment.” U.S. Compl.
6 ¶ 58.

7 Risk adjustment is accomplished by assigning each beneficiary a risk score, which “acts as
8 a multiplier that is applied to the MA plan’s base rate to determine the overall monthly payment
9 for the beneficiary.” U.S. Compl. ¶ 58. A beneficiary’s risk score is determined through a model
10 called the CMS Hierarchical Conditions Category (“HCC”) model, which, as indicated above, is
11 based on the patient’s demographic factors and health status. *See* U.S. Compl. ¶ 59. “The CMS-
12 HCC model is prospective in the sense that it uses diagnoses made in a base year (the ‘service
13 year’), along with demographic information (such as age and gender, among others), to predict
14 costs for Medicare benefits and adjust payments for the following year (the ‘payment year’).” U.S.
15 Compl. ¶ 60.

16 With respect to health status, the model relies on diagnosis codes from the International
17 Classification of Diseases (“ICD”). *See* U.S. Compl. ¶ 60. “ICD diagnosis codes are
18 alphanumeric codes used by healthcare providers, insurance companies, and public health
19 agencies to represent medical conditions; every disease, injury, infection, and symptom has its
20 own code.” U.S. Compl. ¶ 62. In general, the more severe an enrollee’s medical diagnoses are,
21 the greater the risk adjustment is, and the more a MA organization is paid. *See* U.S. Compl. ¶ 2
22 (alleging that “CMS adjusts these payments for various ‘risk’ factors that affect expected
23 healthcare expenditures, to ensure that MA Organizations are paid more for sicker enrollees
24 expected to incur higher healthcare costs and less for healthier enrollees expected to incur lower
25 costs”); U.S. Compl. ¶ 3 (alleging that “the amount of payment that CMS made to [a MA
26 organization] for a Medicare Advantage patient depended directly on the diagnoses that [the MA
27 organization] submitted to CMS for that patient”).

28 To participate in Medicare Advantage, a MA organization “must enter into and execute a

1 written contract with CMS for the MA plans [it] operate[s].” U.S. Compl. ¶ 74. According to the
 2 government, both under its contract with CMS and under federal regulations, a MA organization is
 3 required to provide CMS with risk adjustment data for its enrollees conforms with not just the ICD
 4 diagnosis codes but also the ICD Guidelines. *See, e.g.*, U.S. Compl. ¶¶ 61, 81. “The ICD
 5 Guidelines impose numerous requirements and limitations on what diagnoses may be coded in a
 6 particular visit and in a particular setting.” U.S. Compl. ¶ 82. For example, “[f]or an outpatient
 7 visit . . . , the ICD Guidelines only permit the coding of documented conditions that [1] both exist
 8 at the visit *and* that [2] ‘require or affect patient care treatment or management.’” U.S. Compl. ¶
 9 83 (emphasis in original; quoting ICD Guidelines).

10 In its complaint, the United States has sued several Kaiser entities. As alleged, “Kaiser
 11 Permanente” is “an integrated health-care consortium comprised of three components: [1] health
 12 plans (‘Health Plans’); [2] physician medical group practices (referred to as ‘Permanente Medical
 13 Groups’); and [3] hospitals.” U.S. Compl. ¶ 19. The Health Plans are MA organizations, and they
 14 contract with the federal government to provide MA plans. In turn, the Permanente Medical
 15 Groups contract with the Health Plans to provide medical services to patients who enroll in the
 16 plans. *See* U.S. Compl. ¶¶ 20-26. The United States has sued those Health Plans and the
 17 Permanente Medical Groups affiliated with California and Colorado (collectively, “Kaiser”).

18 According to the United States,

19 Kaiser engaged in a coordinated scheme to unlawfully obtain
 20 payments from the Medicare Part C program Kaiser obtained
 21 these payments by systematically altering patient medical records to
 22 add diagnoses that either [1] did not exist or [2] were unrelated to
 23 the patient’s visit with the Kaiser physician. Kaiser altered the
 24 patients’ medical records to add these diagnoses retrospectively –
 25 after the patient medical visit – using a mechanism called an
 26 addendum. Often, these addenda were added months or even a year
 27 or more after the visit. In many cases, patients were not even told
 28 that they supposedly had the diagnoses that Kaiser had added to
 their medical records. Kaiser knew that it could not lawfully submit
 diagnoses that were unrelated to the patient’s visit, but it
 nevertheless routinely used these diagnoses to obtain additional
 payments from Medicare. Between 2009 and 2018, Kaiser added
 roughly half a million diagnoses using addenda. Kaiser submitted
 the diagnoses from these addenda to the Centers for Medicare and
 Medicaid Services (“CMS”) and received additional Medicare
 payments in the range of \$1 billion from these diagnoses.

1 U.S. Compl. ¶ 1; *see also* U.S. Compl. ¶ 7 (referring to practices such as “data mining,” “chart
2 review,” and “refreshing” that Kaiser used to find diagnoses to add); Opp’n at 7 (discussing the
3 above practices of data mining, chart review, and refreshing).

4 Based on, *inter alia*, the above allegations, the government has asserted the following
5 causes of action:

- 6 (1) Violation of the federal False Claims Act (“FCA”) by presenting or causing to be
7 presented false claims for “risk-adjustment payments in the form of improper
8 diagnoses codes for Defendants’ Medicare patients, in violation of CMS
9 regulations and policies, which Defendants agreed to and were obligated to comply
10 with.” U.S. Compl. ¶ 349; *see also* 31 U.S.C. § 3729(a)(1);.
- 11 (2) Violation of the FCA by “making, using, and causing to be made or used, false
12 records or statements material to false or fraudulent claims resulting in
13 [Defendants’] receiving inflated Medicare payments from CMS to which they were
14 not entitled.” U.S. Compl. ¶ 352; *see also* 31 U.S.C. § 3729(a)(1)(B).
- 15 (3) Violation of the FCA by conspiring “to submit and cause the submission of false
16 claims and to make, use, and cause to make or use, false records and statements
17 material to false or fraudulent claims to the United States and use false records and
18 statements material to false or fraudulent claims.” U.S. Compl. ¶ 357; *see also* 31
19 U.S.C. § 3729(a)(1)(C).
- 20 (4) Payment by mistake.
- 21 (5) Unjust enrichment.

22 II. DISCUSSION

23 A. Legal Standard

24 Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include “a short and plain
25 statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). A
26 complaint that fails to meet this standard may be dismissed pursuant to Federal Rule of Civil
27 Procedure 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6). To overcome a Rule 12(b)(6) motion to dismiss
28 after the Supreme Court’s decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic*

1 *Corp. v. Twombly*, 550 U.S. 544 (2007), a plaintiff’s “factual allegations [in the complaint] ‘must
2 . . . suggest that the claim has at least a plausible chance of success.’” *Levitt v. Yelp! Inc.*, 765
3 F.3d 1123, 1135 (9th Cir. 2014). The court “accept[s] factual allegations in the complaint as true
4 and construe[s] the pleadings in the light most favorable to the nonmoving party.” *Manzarek v. St.
5 Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But “allegations in a
6 complaint . . . may not simply recite the elements of a cause of action [and] must contain sufficient
7 allegations of underlying facts to give fair notice and to enable the opposing party to defend itself
8 effectively.” *Levitt*, 765 F.3d at 1135 (internal quotation marks omitted). “A claim has facial
9 plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable
10 inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. “The
11 plausibility standard is not akin to a probability requirement, but it asks for more than a sheer
12 possibility that a defendant has acted unlawfully.” *Id.* (internal quotation marks omitted).

13 B. FCA Claims

14 1. General Law

15 “[T]he essential elements of False Claims Act liability are: (1) a false statement or
16 fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the
17 government to pay out money or forfeit moneys due.” *United States ex rel. Campie v. Gilead
18 Scis.*, 862 F.3d 890, 902 (9th Cir. 2017); *see also United States v. Corinthian Colls.*, 655 F.3d 984,
19 992 (9th Cir. 2011).

20 With respect to the first element, a claim for payment can be factually false or legally false.
21 “A factually false claim is one in which ‘the claim for payment is itself literally false or
22 fraudulent,’ such as when the claim ‘involves an incorrect description of goods or services
23 provided or a request for reimbursement for goods or services never provided.’” *United States ex
24 rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667, 675 (9th Cir. 2018); *see also United States ex rel.
25 Druding v. Druding*, 952 F.3d 89, 96 (3d Cir. 2020) (noting that there is factual falsity “when the
26 facts contained within the claim are untrue”).

27 A legally false claim generally involves a “‘knowingly false certification of compliance
28 with a regulation or contractual provision as a condition of payment.’” *United States ex rel.*

1 *Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018); *see also United States ex rel.*
 2 *Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018) (stating that a claim “is
 3 legally false when the claimant lies about its compliance with a statutory, regulatory, or
 4 contractual requirement”). “[L]egal falsity can be express, such as a false affirmative statement of
 5 compliance with a statutory, regulatory, or contractual prerequisite, or it can be implied – for
 6 instance, the absence of a material disclosure that would have prevented compliance with a
 7 statutory, regulatory, or contractual prerequisite.” *Druding*, 952 F.3d at 96; *see also Silingo*, 904
 8 F.3d at 675-76 (stating that “[e]xpress false certification involves an entity’s representation of
 9 compliance with the law as part of the process for submitting a claim when it is actually not
 10 compliant,” while “[i]mplied false certification occurs when an entity has previously undertaken
 11 to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting
 12 a claim for payment even though a certification of compliance is not required in the process of
 13 submitting the claim”).

14 The Supreme Court addressed the theory of implied false certification in *Universal Health*
 15 *Services v. United States ex rel. Escobar*, 579 U.S. 176 (2016) (hereinafter “*Escobar*”). In
 16 *Escobar*, a teenager was a beneficiary of Massachusetts’s Medicaid program and was receiving
 17 counseling services at a mental health facility in Massachusetts. The teens’ parents filed suit after
 18 learning that few employees at the facility were actually licensed to provide mental health
 19 counseling and that supervision of them was minimal. *See id.* at 183-84. They asserted “an
 20 implied false certification theory of liability” – *i.e.*, the defendant “submitted reimbursement
 21 claims that made representations about the specific services provided by specific types of
 22 professionals, but that failed to disclose serious violations of regulations pertaining to staff
 23 qualifications and licensing requirements for these services.” *Id.* at 184-85.

24 The Supreme Court took note that there is a

25 rule that half-truths – representations that state the truth only so far
 26 as it goes, while omitting critical qualifying information – can be
 actionable misrepresentations. . . .

27 So too here, by submitting claims for payment using payment codes
 28 that corresponded to specific counseling services, [the defendant]
 represented that it had provided individual therapy, family therapy,

1 preventive medication counseling, and other types of treatment.
 2 Moreover, [facility] staff members allegedly made further
 3 representations in submitting Medicaid reimbursement claims by
 4 using National Provider Identification numbers corresponding to
 5 specific job titles. And these representations were clearly
 6 misleading in context. Anyone informed that a social worker at a
 7 Massachusetts mental health clinic provided a teenage patient with
 8 individual counseling services would probably – but wrongly –
 9 conclude that the clinic had complied with core Massachusetts
 10 Medicaid requirements (1) that a counselor “treating children [is]
 11 required to have specialized training and experience in children’s
 12 services,” and also (2) that, at a minimum, the social worker
 13 possesses the prescribed qualifications for the job. By using
 14 payment and other codes that conveyed this information without
 15 disclosing [the facility’s] many violations of basic staff and
 16 licensing requirements for mental health facilities, [the defendant’s]
 17 claims constituted misrepresentations. By using payment and other
 18 codes that conveyed this information without disclosing [the
 19 facility’s] many violations of basic staff and licensing requirements
 20 for mental health facilities, [the defendant’s] claims constituted
 21 misrepresentations.

22 Accordingly, we hold that the implied certification theory can be a
 23 basis for liability, at least where two conditions are satisfied: First,
 24 the claim does not merely request payment, but also makes specific
 25 representations about the goods or services provided; and second,
 26 the defendant’s failure to disclose noncompliance with material
 27 statutory, regulatory, or contractual requirements makes those
 28 representations misleading half-truths.

16 *Id.* at 189-90.

17 For the second element, *i.e.*, scienter, a person “knowingly” submits false information if he
 18 or she “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or
 19 falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the
 20 information.” 31 U.S.C. § 3729(b)(1)(A). A defendant cannot be held liable for an “[i]nnocent
 21 mistake” or “mere negligence,” *U.S. ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d
 22 1416, 1421 (9th Cir. 1991), but “no proof of specific intent to defraud” is required. 31 U.S.C. §
 23 3729(b)(1)(B).

24 Regarding the third element of an FCA claim, *i.e.*, materiality, “the term ‘material’ means
 25 having a natural tendency to influence, or be capable of influencing, the payment or receipt of
 26 money or property.” *Id.* § 3729(b)(4). “[The] materiality requirement descends from ‘common-
 27 law antecedents.’” *Escobar*, 579 U.S. at 193.

28 Under any understanding of the concept, materiality “look[s] to the

1 effect on the likely or actual behavior of the recipient of the alleged
2 misrepresentation.” In tort law, for instance, a “matter is material”
3 in only two circumstances: (1) “[if] a reasonable man would attach
4 importance to [it] in determining his choice of action in the
5 transaction”; or (2) if the defendant knew or had reason to know that
6 the recipient of the representation attaches importance to the specific
7 matter “in determining his choice of action,” even though a
8 reasonable person would not. Materiality in contract law is
9 substantially similar

10 The materiality standard is demanding. The False Claims Act is not
11 “an all-purpose antifraud statute,” or a vehicle for punishing garden-
12 variety breaches of contract or regulatory violations. A
13 misrepresentation cannot be deemed material merely because the
14 Government designates compliance with a particular statutory,
15 regulatory, or contractual requirement as a condition of payment.
16 Nor is it sufficient for a finding of materiality that the Government
17 would have the option to decline to pay if it knew of the defendant’s
18 noncompliance. Materiality, in addition, cannot be found where
19 noncompliance is minor or insubstantial.

20 In sum, when evaluating materiality under the False Claims Act, the
21 Government’s decision to expressly identify a provision as a
22 condition of payment is relevant, but not automatically dispositive.
23 Likewise, proof of materiality can include, but is not necessarily
24 limited to, evidence that the defendant knows that the Government
25 consistently refuses to pay claims in the mine run of cases based on
26 noncompliance with the particular statutory, regulatory, or
27 contractual requirement. Conversely, if the Government pays a
28 particular claim in full despite its actual knowledge that certain
requirements were violated, that is very strong evidence that those
requirements are not material. Or, if the Government regularly pays
a particular type of claim in full despite actual knowledge that
certain requirements were violated, and has signaled no change in
position, that is strong evidence that the requirements are not
material.

19 *Id.* at 193.

20 Thus, under *Escobar*, factors that should be considered on materiality include the
21 following:

22 (1) “the Government’s decision to expressly identify a provision as a
23 condition of payment”; (2) whether “the Government consistently
24 refuses to pay claims in the mine run of cases based on
25 noncompliance with the particular statutory, regulatory, or
26 contractual requirement” or if, with actual knowledge of the non-
27 compliance, it consistently pays such claims and there is no
28 indication that its practice will change; and (3) whether the
“noncompliance is minor or insubstantial” or if it goes “to the very
essence of the bargain.”

27 *United States ex rel. Prather v. Brookdale Senior Living Cmty., Inc.*, 892 F.3d 822, 831 (6th Cir.
28 2018); *see also United States ex rel. Ling v. City of L.A.*, No. CV 11-974 PSG (JCx), 2018 U.S.

1 Dist. LEXIS 136589, at *36 (C.D. Cal. July 25, 2018) (identifying the same basic considerations).

2 2. Government’s Liability Theories

3 As a preliminary matter, the Court considers what the government’s theories of liability are
4 and whether those theories are predicated on factual falsity, legal falsity, or both.

5 As noted above, the gist of the government’s complaint is that Kaiser submitted false
6 claims for payment because it “alter[ed] patient medical records to add diagnoses that either [1]
7 did not exist or [2] were unrelated to the patient’s visit with the Kaiser physician.” U.S. Compl. ¶
8 1.

9 With respect to (1), only factual falsity is implicated. If a diagnosis of a medical condition
10 was claimed but that medical condition did not exist (*i.e.*, the diagnosis was “clinically
11 inaccurate,” Reply at 1), then a claim for payment based on that diagnosis is literally false. *See*
12 *Silingo*, 904 F.3d at 675 (“A factually false claim is one in which ‘the claim for payment is itself
13 literally false or fraudulent,’ such as when the claim ‘involves an incorrect description of goods or
14 services provided or a request for reimbursement for goods or services never provided.’”);
15 *Druding*, 952 F.3d at 96 (noting that there is factual falsity “when the facts contained within the
16 claim are untrue”).

17 With respect to (2), there is both factual falsity and legal falsity.² There is factual falsity
18 because a claim for payment was based on a diagnosis of a medical condition that did exist, *but*
19 the condition did not “require[] or affect[] patient care, treatment, or management for the visit.”
20 U.S. Compl. ¶ 87; *see also* Opp’n at 16-17 (noting that, “when Kaiser submitted for payment
21 inaccurate ICD codes in contravention of the ICD Guidelines, those were factually false claims
22 because they incorrectly described the valid ICD codes for the patient visit”). There is legal falsity
23 because – as claimed by the government – both the CMS/Kaiser contract and federal regulations
24 required Kaiser to comply with the ICD Guidelines, and “the ICD Guidelines only permit the
25

26 _____
27 ² There does not appear to be anything that would prevent a claim for payment from being both
28 factually false and legally false (in the appropriate circumstances). The Third Circuit has noted
that “legal falsity necessarily encompasses situations of factual falsity, for instance, where a
physician’s lies about medical test results would render certifications for reimbursement
inaccurate and non-compliant with regulations.” *Druding*, 952 F.3d at 96-97.

1 coding of documented conditions that [1] both exist at the visit *and* that [2] ‘require or affect
2 patient care treatment or management.’” U.S. Compl. ¶ 83 (emphasis in original; quoting ICD
3 Guidelines); *see also Polukoff*, 895 F.3d at 741 (stating that a legally false claim involves a
4 “‘knowingly false certification of compliance with a regulation or contractual provision as a
5 condition of payment’”).

6 The government’s complaint largely seems to focus on the second theory of liability. *See*
7 *also* Opp’n at 16 (suggesting that “the Court need not [even] reach Kaiser’s argument that the
8 Complaint fails to allege Kaiser submitted ‘factually false’ claims for non-existent diagnoses”
9 because the second theory of liability – *i.e.*, “Kaiser’s submission of diagnoses that did not require
10 or affect patient care, treatment, or management, in violation of the [ICD] Guidelines” – is viable).
11 However, the Court begins with an evaluation of the first theory of liability because, as Kaiser
12 argues, if that theory is indeed viable, it significantly expands the scope of the case. *See* Reply at
13 1-2 (“It is imperative for the Court to decide now whether the United States can prosecute
14 allegations of clinical falsity because discovery regarding such allegations will be broad and
15 voluminous. To support such a fraud theory, the United States will need to prove that each
16 Medicare Advantage member at issue did not have the diagnosed condition and Defendants will be
17 entitled to documentary and testimonial discovery to rebut that proof.”).

18 3. Diagnoses That Did Not Exist/Clinically Inaccurate Diagnoses

19 For the government’s first theory of liability – that Kaiser had patient medical records
20 amended to add diagnoses that did not exist (*i.e.*, were clinically inaccurate) – Kaiser makes two
21 arguments: (1) the government has failed to plead factual falsity and (2) the government has failed
22 to plead knowledge of falsity on the part of Kaiser.

23 a. Falsity

24 As an initial matter, the Court notes that the government has sufficiently pled three specific
25 instances of clinically inaccurate diagnoses in paragraphs 338, 339, and 210-11 of its complaint.

- 26 • In paragraph 338, the government describes an incident relating to “Patient #2.”
27 Patient #2 was seen by a Kaiser doctor on 5/30/2012 “for a blood pressure check
28 and to review lab results.” U.S. Compl. ¶ 338(a). Six months after the visit, a

1 Kaiser coder contacted the doctor, informing the doctor that Patient #2 had
 2 “several uncoded diagnoses the region thinks should be picked up” – including
 3 prostate cancer. U.S. Compl. ¶ 338(c). The medical record from the original visit
 4 indicated that “Patient #2 had a *history of* prostate cancer (identified with a
 5 different ICD history code) and did not have active prostate cancer.” U.S. Compl.
 6 ¶ 338(d) (emphasis in original). Nevertheless, the doctor responded to the query by
 7 creating an addendum to add, *inter alia*, a diagnosis of prostate cancer. *See* U.S.
 8 Compl. ¶ 338(e).

- 9 • In paragraph 339, the government describes an incident relating to “Patient #3.”
 10 Patient #3 was seen by a Kaiser doctor on 1/17/2013 for shortness of breath. He
 11 was diagnosed with exacerbation of chronic obstructive pulmonary disease
 12 (“COPD”). The doctor ordered a chest x-ray to rule out pneumonia. The results of
 13 the x-ray showed that Patient #3 did not have pneumonia. *See* U.S. Compl. ¶
 14 339(a). Approximately eight months later, a Kaiser data quality trainer contacted
 15 the doctor, informing him that “the imaging you ordered showed Positive Aortic
 16 Atherosclerosis” and asking him to amend his medical notes to “capture” AA.
 17 U.S. Compl. ¶ 339(c). The doctor responded to the query by adding a diagnosis of
 18 AA via an addendum. *See* U.S. Compl. ¶ 339(d). The doctor later created two
 19 more addenda, ultimately adding “twelve more diagnoses to Patient #3’s medical
 20 record.” U.S. Compl. ¶ 339(h). One of these diagnoses was for severe obesity
 21 equivalent; however, this diagnosis was not justified because it “requires a BMI of
 22 at least 35” and Patient #3’s BMI at the time of the visit was only 31. U.S. Compl.
 23 ¶ 339(i).

- 24 • In paragraphs 210-11, the government alleges that, in Colorado, Kaiser used to data
 25 mine and query doctors to add hypoxia for patients receiving oxygen; however,
 26 after CMS removed hypoxia as a condition from the HCC model, Kaiser queried
 27 doctors to add different diagnoses – acute and/or chronic respiratory failure and
 28 obesity hypoventilation syndrome. *See* U.S. Compl. ¶ 210. On one occasion, a

1 doctor in Colorado “created an addendum to add the diagnosis of obesity
 2 hypoventilation syndrome – a breathing disorder found in some *obese* individuals –
 3 to a patient who was clearly *not* obese (she was 5’9” and weighed 108 pounds).”
 4 U.S. Compl. ¶ 211 (emphasis in original).

5 However, presumably, the government has not filed suit to seek relief for these three
 6 specific instances alone – *i.e.*, it is essentially claiming that Kaiser had a *scheme* to include to
 7 include nonexistent diagnoses in patients’ medical records. These three specific examples,
 8 however, are not enough to make out a plausible case for such a systemic scheme. The complaint
 9 does not contain specific allegations which plausibly establish these three instances were
 10 emblematic of a wider pattern of similar practices.

11 On the other hand, the Court concludes that the government has alleged a plausible scheme
 12 with respect to one specific disease in particular – *i.e.*, cachexia. In its pleading, the government
 13 has alleged as follows: “Cachexia is a complex metabolic syndrome associated with physical
 14 wasting, weight loss and muscle atrophy.” U.S. Compl. ¶ 207. A diagnosis of cachexia “is based
 15 on clinical judgment rather than clinical indicators,” U.S. Compl. ¶ 295 – which implicitly makes
 16 it more vulnerable to exploitation. According to the government, in 2009, as part of a training,
 17 “the N. California Medical Group identified cachexia as one of a few diagnoses that would help
 18 them ‘Find \$100 million dollars in NCal.’”; then, in or about 2011, “the N. California Medical
 19 Group created a data-mining algorithm to identify potential cachexia diagnoses,” and the results of
 20 the algorithm were “sent to physicians with queries for them to addend their patient medical
 21 records to add cachexia diagnoses.” U.S. Compl. ¶ 295. Queries were “routinely” sent to doctors
 22 to add diagnoses of cachexia even “for patients who were merely thin.” U.S. Compl. ¶ 296; *cf.*
 23 U.S. Compl. ¶ 296 (noting that cachexia “is not simply low body weight”). As a result,
 24 “physicians in Northern California added cachexia via addenda over *120 times* more than
 25 physicians in Southern California and Colorado, regions that did not have a cachexia initiative.”
 26 U.S. Compl. ¶ 300 (emphasis in original). Furthermore, audits revealed that “many of these
 27 diagnoses were invalid[] because the patient did not . . . have cachexia.” U.S. Compl. ¶ 300.
 28 Specifically, as part of an audit, “the Clinical Review Team (within [the Encounter Information

1 Operations office]) found that *over 90%* of the time a physician added the cachexia diagnosis
2 based on a Kaiser query, the documentation is ‘either lacking or contradict[s] the definition of
3 Cachexia.’” U.S. Compl. ¶ 321 (emphasis added); *see also* U.S. Compl. ¶ 346(f) (discussing
4 Patient #10, whose doctor created an addendum to add cachexia as a diagnosis even though the
5 doctor stated “‘patient has no general debility’” and only “‘lost some lbs of weight’”). Based on
6 the above allegations, the government has sufficiently alleged that Kaiser had a scheme to include
7 to include nonexistent diagnoses of cachexia in patients’ medical records.

8 Kaiser protests that the fact that “the medical-record documentation was ‘lacking’ or
9 inconsistent say[s] nothing about the member’s actual health status” – especially since cachexia is
10 (as alleged) based on clinical judgment rather than clinical indicators. Reply at 7-8. Although
11 Kaiser’s argument is not without some merit, at this juncture all reasonable inferences are to be
12 made in the government’s favor. If documentation was lacking or if documentation contradicted
13 the definition of cachexia, then it can reasonably be inferred that a diagnosis of cachexia was not
14 justified. Thus, based on the government’s allegations, it can reasonably be inferred that a large
15 number of cachexia diagnoses, which were made through addenda, were literally false.

16 Hence, thus far, the only systemic scheme sufficiently alleged by the government relates to
17 cachexia only. Admittedly, if Kaiser (as alleged) was willing to make clinically false diagnoses
18 for cachexia, one could imagine that Kaiser could easily have had a scheme far broader in scope,
19 reaching any number of medical conditions as well. But at this point, given the allegations in the
20 complaint, it cannot reasonably be inferred that Kaiser’s scheme was broader in scope. The
21 government has leave to amend its complaint if it wishes to expand the scope of its allegations on
22 clinically false diagnoses. Identifying scattered anecdotes alone will not suffice.

23 b. Knowledge

24 The next issue raised by Kaiser is whether the government has sufficiently pled the
25 element of knowledge. The Court considers this issue only with respect to the allegedly false
26 cachexia diagnoses. As noted above, under the FCA, a person “knowingly” submits false
27 information if he or she “(i) has actual knowledge of the information; (ii) acts in deliberate
28 ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or

1 falsity of the information.” 31 U.S.C. § 3729(b)(1)(A). A defendant cannot be held liable for an
2 “[i]nnocent mistake” or “mere negligence,” *U.S. ex rel. Hagood v. Sonoma Cnty. Water Agency*,
3 929 F.2d 1416, 1421 (9th Cir. 1991), but “no proof of specific intent to defraud” is required. 31
4 U.S.C. § 3729(b)(1)(B).

5 Given that reckless disregard can satisfy the knowledge requirement and that all reasonable
6 inferences are to be made in the government’s favor at this early stage, the government has alleged
7 enough with respect to scienter. According to the government, Kaiser higher-ups were warned
8 about sending queries to doctors prompting them to add diagnoses for cachexia. *See, e.g.*, U.S.
9 Compl. ¶ 297 (“After noting that physicians were protesting that naturally thin patients did not
10 have cachexia, Dr. Inna Ravkin (an internal medicine physician in Northern California) warned
11 Karen Graham^[3] and Dr. David Bliss^[4] in 2011 that the prompting would result in ‘inappropriate
12 assignment of this diagnosis.’”); U.S. Compl. ¶ 298 (“Also in 2011, Dr. Patrick Kan (a CMS Lead)
13 reported to Dr. David Bliss and Karen Graham that ‘they [the treating physicians] do not see any
14 physical signs of cachexia.’”); U.S. Compl. ¶ 299 (“And in 2013, Norma Gonzalez (a Senior
15 Consultant for CMS matters) wrote to Danielle Sheetenhelm (Clinical Review Manager) that
16 because she had ‘a couple of thousand datamining diagnoses in my area,’ it would be ‘impossible’
17 to review them all. She further stated that the feedback from the physicians was that the queries
18 were ‘garbage.’”). If responsible persons at Kaiser were warned, then Kaiser was on notice and a
19 failure to act in response to indications of inaccurate diagnoses could reasonably be deemed
20 reckless disregard of the falsity of cachexia diagnoses.

21 Reckless disregard could also be inferred based on allegations that queries were being sent
22 to doctors about cachexia diagnoses simply because the patients at issue were thin. That a
23 cachexia diagnoses is based on a clinical judgment does not mean that Kaiser was justified in
24 prompting doctors about diagnosing cachexia simply because of an underweight patient. It may
25

26 ³ As alleged, Ms. Graham was the Managing Director of the N. California Medical Group’s
27 Encounter Information Operations office. *See* U.S. Compl. ¶ 119.

28 ⁴ As alleged, Dr. Bliss was the N. California Medical Group Regional Director of Documentation
and Coding. *See* U.S. Compl. ¶ 248.

1 be inferred that Kaiser officials were looking for the results Kaiser allegedly obtained.

2 Finally, the government has alleged that an audit revealed a high error rate with respect to
 3 cachexia diagnoses made through addenda but that Kaiser failed to respond. *See* U.S. Compl. ¶
 4 322 (“Despite this knowledge [about the audit], the N. California Medical Group did not modify
 5 its cachexia data-mining algorithm or stop-prompt program for several years.”). This further
 6 supports a finding of scienter. For false cachexia diagnoses thereafter, one could reasonably infer
 7 reckless disregard on the part of Kaiser.

8 4. Diagnoses Unrelated to Doctors’ Visits

9 As noted above, the government’s second theory of liability – that Kaiser altered patient
 10 medical records by adding diagnoses that were not related to the doctors’ visits – is its main one.
 11 And as noted above, this theory of liability implicates both factual falsity and legal falsity. In its
 12 papers, Kaiser argues that the government has failed to adequately plead falsity for the second
 13 theory of liability. Kaiser further argues that, even if falsity were adequately pled, the government
 14 still has not sufficiently pled materiality.

15 a. Falsity

16 As an initial matter, the Court notes that Kaiser seems to have ignored the fact that the
 17 second theory of liability can be construed as being predicated on factual falsity. *See* Opp’n at 16-
 18 17 (noting that, “when Kaiser submitted for payment inaccurate ICD codes in contravention of the
 19 ICD Guidelines, those were factually false claims because they incorrectly described the valid ICD
 20 codes for the patient visit”). Because the Court agrees with the government that factual falsity is
 21 implicated, then that alone is a sufficient basis for the Court to reject Kaiser’s argument that falsity
 22 has not been sufficiently alleged.

23 Even if the Court were to consider only legal falsity, Kaiser would fare no better. A
 24 legally false claim for payment involves an assertion (either express or implied) that there is
 25 compliance with a statute, regulation, or contract. *See, e.g., Escobar*, 579 U.S. at 181 (“[L]iability
 26 can attach when the defendant submits a claim for payment that makes specific representations
 27 about the goods or services provided, but knowingly fails to disclose the defendant’s
 28 noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances,

1 liability may attach if the omission renders those representations misleading.”). In the case at bar,
 2 the government argues that both the CMS/Kaiser contract and federal regulations required Kaiser
 3 to comply with ICD Guidelines – and under the ICD Guidelines, a diagnosis can be made on a
 4 medical record only if it required or affected patient care treatment or management at the doctor’s
 5 visit. In response, Kaiser contends that the neither the contract nor regulations required Kaiser to
 6 comply with the ICD Guidelines – and therefore the ICD Guidelines are at best “subregulatory”
 7 documents that lack the force of law.⁵ Kaiser underscores that the Medicare Act contains the
 8 following provision:

9 No rule, requirement, or other statement of policy (other than a
 10 national coverage determination) that establishes or changes a
 11 substantive legal standard governing the scope of benefits, the
 12 payment for services, or the eligibility of individuals, entities, or
 organizations to furnish or receive services or benefits under this
 subchapter shall take effect unless it is promulgated by the Secretary
 by regulation under paragraph (1).

13 42 U.S.C. § 1395hh(a)(2).⁶ In *Azar v. Allina Health Services*, the Supreme Court noted that, under
 14 § 1395hh(a)(2), “Congress has told the government that, when it wishes to establish or change a
 15 ‘substantive legal standard’ affecting Medicare benefits, it must first afford the public notice and a
 16 chance to comment.” *Allina*, 139 S. Ct. at 1808.

17 i. Contract

18 As noted above, the government contends as an initial matter that Kaiser is bound by the
 19 ICD Guidelines because the CMS/Kaiser contract requires compliance with the Guidelines.

20 A copy of the CMS/Kaiser contract can be found at Exhibit I to Kaiser’s RJN. Article II.A

21 _____
 22 ⁵ To the extent Kaiser has argued that there is no contractual provision or regulation cited by the
 23 government that expressly applies to *addenda* of medical records (*i.e.*, the means by which Kaiser
 24 allegedly achieved its upcoding), the government correctly contends that this is a red herring. *See*
 25 *Opp’n* at 15 (“[A]n addendum is merely a change to the medical record for a patient visit made
 26 after the close of that visit record. Nothing in Kaiser’s contracts, the relevant regulations, or the
 27 ICD Guidelines indicates that diagnoses added after patient visits are subject to different
 28 standards.”). Notably, Kaiser somewhat backtracked from this argument in its reply brief. *See*
Reply at 10 n.7 (“Defendants agree [that there is no ‘addenda exception’], but because the United
 States’ case rests entirely on coding from addenda, the Motion focuses on the standards that apply
 to such coding. And the Court’s decision can be similarly narrow.”).

⁶ “While the APA requires many other agencies to offer public notice and a comment period
 before adopting new regulations, it does not apply to public benefit programs like Medicare.”
Azar v. Allina Health Servs., 139 S. Ct. 1804, 1808 (2019).

1 of the contract provides as follows: “The MA Organization agrees to operate one or more
2 coordinated care plans . . . and in compliance with the requirements of this contract and applicable
3 Federal statutes, regulations, *and policies (e.g., policies as described in the Call Letter, Medicare*
4 *Managed Care Manual, etc.)*.” Def.’s RJN, Ex. I (CMS/Kaiser Contract, art. II.A) (emphasis
5 added). The Medicare Managed Care Manual contains a chapter – Chapter 7 – on “Risk
6 Adjustment.” *See* Def.’s RJN, Ex. C (CMS/Kaiser Contract Ch. 7). There are twelve sections in
7 Chapter 7. The fourth section (§ 40) covers the “Role and Responsibilities of Plan Sponsors,”
8 which include MA organizations. With respect to risk adjustment data submission requirements, §
9 40 states in relevant part as follows:

10 Medicare Advantage Organizations (MAOs) . . . must . . . [e]nsure
11 the accuracy and integrity of risk adjustment data submitted to CMS.
12 All diagnosis codes submitted must be documented in the medical
13 record and must be documented as a result of a face-to-face visit.
14 *The diagnosis must be coded according to [the ICD Guidelines].*

13 Def.’s RJN, Ex. C (CMS Medicare Managed Care Manual, Ch. 7, § 40) (emphasis added); *see*
14 *also* U.S. Compl. ¶ 81.

15 Accordingly, based on the Article II.A of the CMS/Kaiser Contract, its incorporation of the
16 CMS Medicare Managed Care Manual, and the Manual’s incorporation of the ICD Guidelines, the
17 government argues that a MA organization must comply with the ICD Guidelines in providing
18 risk adjustment data to CMS.

19 In response, Kaiser makes several arguments, none of which is convincing.

20 First, Kaiser contends that the government’s reliance on Article II.A is flawed:

21 The location of [this] clause . . . confirms that the contract does not
22 require MAOs to comply with nonbinding guidance in order to
23 receive payment from CMS. The clause appears in Article II of the
24 contract, which describes the network and benefit structures of a
25 coordinated care plan. But the section that addresses *payment* is
26 Article IV, which does not reference subregulatory guidance at all
27 and cites only statutes and regulations.

25 Mot. at 17 (emphasis in original); *see also* Reply at 10-11 (arguing that Article II “concerns plan
26 design” or “plan structure”). But this argument is questionable if only because Kaiser’s
27 characterization of Article II is not on point. Article II is titled “Coordinated Care Plan.” The
28 article simply lays out broad principles – *e.g.*, Article II.A provides that the MA organization

1 agrees to operate a coordinated care plan(s) and in compliance with federal law and policies;
 2 Article II.B provides that the contract incorporates changes required by statute to be implemented
 3 during the term of the contract; Article III.C provides that, other than at the beginning of a
 4 calendar year, CMS will not implement regulatory requirements that impose new significant costs
 5 or burdens on the MA organization; etc. Nothing about the article is limited or targeted to plan
 6 design or plan structure, as Kaiser claims. Indeed, it is notable that Article II.A refers to now a
 7 coordinated care plan is to be *operated*.

8 In any event, just because the reference to compliance with CMS policies (including the
 9 Manual which then incorporates the ICD Guidelines) is in Article II and not in Article IV does not
 10 mean that compliance with ICD Guidelines is not required for risk adjustment data. As the
 11 government correctly contends, although “Kaiser argues that it is not bound by this term because it
 12 appears at the beginning of the contract[] rather than in the payment section, . . . there is no such
 13 rule of contract law.” Opp’n at 11.

14 Second, Kaiser argues that it would be improper for it to be bound by the ICD Guidelines
 15 as a result of two general incorporations by reference (*i.e.*, incorporation of the Manual which then
 16 incorporates the Guidelines):

17 [T]he government cannot seriously contend that the broad, non-
 18 specific language of the contract provision means that the Health
 19 Plan Defendants must adhere to every word of the ICD Guidelines
 20 simply because they are generally referenced in the [Manual], which
 itself is referenced in a parenthetical in a single sentence of a CMS
 contract.

21 Mot. at 17; *see also* Reply at 11. This argument is unpersuasive, especially in the context of this
 22 instant case. Kaiser is a sophisticated entity and incorporation by reference is a common
 23 contractual tool. It defies reality to suggest a contract is too complicated for an entity like Kaiser
 24 to understand. In any event, ICD Guidelines and their importance to medical procedure is not
 25 some obscure bit of minutiae. Further, the government has alleged here that Kaiser was in fact
 26 well aware of the ICD Guideline requirement at issue. *See, e.g.*, U.S. Compl. ¶¶ 88-96 (alleging
 27 that, “[a]s far back as 2008,” Kaiser had issued to all regions a “Program Advisory” which was
 28 “intended to clarify the minimum amount and type of documentation necessary to support the

1 diagnoses submitted to [CMS] as Medicare Advantage risk adjustment data”]; the Program
 2 Advisory specified, *inter alia*, that documentation must comply with the ICD Guidelines).
 3 Finally, it is worth noting that, as a practical matter, Kaiser’s concerns are essentially addressed
 4 through the FCA requirement of materiality (*i.e.*, that the false statement must have been material,
 5 causing the government to pay out money). *See Campie*, 862 F.3d at 902.

6 Third, Kaiser points out that the CMS/Kaiser contract specifies that federal
 7 statutes/regulations should prevail if there is a conflict between such and the contract. *See* Def.’s
 8 RJN, Ex. I (CMS/Kaiser Contract, art. IX.D) (“In the event that any provision of this contract
 9 conflicts with the provisions of any statute or regulation applicable to an MA Organization, the
 10 provisions of the statute or regulation shall have full force and effect.”). Kaiser then argues that
 11 “[a]llowing CMS to create contractual obligations that are not reflected in the Medicare Act or any
 12 regulations guts Congress’s intent to require notice-and-comment rulemaking for gap-filling
 13 guidance.” Mot. at 18 (referring to § 1395hh(a)(2) of the Medicare Act and the Supreme Court’s
 14 decision in *Allina*). *See, e.g., Allina*, 139 S. Ct. at 1808 (noting that, under § 1395hh(a)(2) of the
 15 Medicare Act, “Congress has told the government that, when it wishes to establish or change a
 16 ‘substantive legal standard’ affecting Medicare benefits, it must first afford the public notice and a
 17 chance to comment”).

18 The government, however, has provided a strong counter-argument – *i.e.*, that “§
 19 1395hh(a)(2) does not address the government’s ability to contract, nor suggest that contractual
 20 terms must first go through notice and comment. The statute applies to the Secretary’s rulemaking
 21 authority, not his contracting authority.” Opp’n at 11. The government also fairly points out that
 22 Congress “*mandated* that the Secretary execute contracts with MAOs.” Opp’n at 12 (emphasis in
 23 original). In fact, Congress even gave some discretion to the Secretary as to contract terms –
 24 specifying that “[t]he contract shall contain such other terms and conditions not inconsistent with
 25 this part [42 U.S.C. § 1395w-21 *et seq.*] . . . as the Secretary may find necessary and appropriate.”
 26 42 U.S.C. § 1395w-27(e)(1). Although there is a statutory limitation that contract terms may not
 27 be “inconsistent with this part,” the government correctly notes that “§ 13955hh(a)(2) is not . . . in
 28 ‘this part’ (*i.e.*, Part C).” Opp’n at 12. There is no statutory bar to incorporation of the ICD

1 Guidelines.

2 Accordingly, the Court rejects Kaiser’s argument that the terms of the CMS/Kaiser
3 contract cannot be read to require compliance with the ICD Guidelines.

4 ii. Federal Regulations

5 Because the Court concludes that the CMS/Kaiser contract requires Kaiser to comply with
6 the ICD Guidelines, it need not address the government’s contention that compliance is also
7 required by federal regulations. However, out of an abundance of caution, the Court has
8 considered the regulatory scheme and concludes it does, in fact, require compliance.

9 The main regulation that supports the government’s position is 42 C.F.R. § 422.310(d)(1).
10 That regulation (which addresses risk adjustment data) provides in relevant part as follows: “MA
11 organizations must submit data that conform to [1] CMS’ requirements for data equivalent to
12 Medicare fee-for-service data, when appropriate, and to [2] all relevant *national standards*.” 42
13 C.F.R. § 422.310(d)(1) (emphasis added). As the government notes, CMS has adopted the ICD
14 code sets for diseases, including the ICD Guidelines, as a national standard – pointing to 45 C.F.R.
15 § 162.1002. *See, e.g.*, 45 C.F.R. § 162.1002(c)(2)(i) (“The Secretary adopts the following
16 maintaining organization’s code sets as the standard medical data code sets: . . . (c) For the period
17 on and after October 1, 2015: . . . (2) International Classification of Diseases, 10th Revision,
18 Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding
19 and Reporting), as maintained and distributed by HHS, for the following conditions: (i)
20 Diseases.”)⁷; *see also* 42 C.F.R. § 422.504(h)(2) (“The MA organization agrees to comply with –
21 . . . (2) HIPAA administrative simplification rules at 45 C.F.R. part[] . . . 162 . . .”).⁸

22 In response, Kaiser argues that § 422.310(d)(1) just addresses “the form of data submitted
23

24 ⁷ In 45 C.F.R. § 1002(a)(1)(i) and § 1002(b)(1), the Secretary essentially adopts the ICD code sets
25 (including the ICD Guidelines) for earlier periods of time.

26 ⁸ The government points out that the ICD code sets for diseases and the related ICD guidelines are
27 also used in the Medicare fee-for-service context, and therefore there is a fair argument that they
28 should be applied in the MA context as well. *See* Opp’n at 13 (adding that “[a]dherence to the
same ICD standard in both traditional Medicare fee-for-service and Medicare Advantage is
important because . . . the risk-adjustment model calculates expected costs for MA patients based
upon Medicare fee-for-service diagnosis data”).

1 to CMS, not the content.” Mot. at 16; *see also* Reply at 14. But nothing about § 422.310(d)(1)
 2 suggests it is limited to the format of data. Moreover, to the extent Kaiser relies on *United States*
 3 *ex rel. Rasmussen*, No. 17-3273-CV-S-BP, 2020 U.S. Dist. LEXIS 137953 (W.D. Mo. Apr. 29,
 4 2020), that case does little, if anything, to support its position. *Rasmussen* addressed an entirely
 5 different subsection of § 422.310 – specifically, § 422.310(g). Furthermore, Kaiser’s attempt to
 6 make an analogy between the § 422.310(g) and § 422.310(d)(1) falls flat. The text of §
 7 422.310(g) is markedly different from that in § 422.310(d)(1), providing as follows: “*Deadlines*
 8 *for submission of risk adjustment data.* Risk adjustment factors for each payment year are based
 9 on risk adjustment data submitted for items and services furnished during the 12-month period
 10 before the payment year that is specified by CMS.” 42 C.F.R. § 422.310(g). Based on, *inter alia*,
 11 this language, the *Rasmussen* court rejected the relator’s argument that “a diagnosis can be coded
 12 only if the patient received treatment for that condition within the past year.” *Rasmussen*, 2020
 13 U.S. Dist. LEXIS 137953, at *17. The court noted: “§ 422.310(g) appears to address the deadline
 14 for submitting risk adjustment data. It is not directed toward specifying the procedure for properly
 15 coding patients’ medical conditions, so it seems to be a poor source for ascertaining such details.”
 16 *Id.* at *19 n.10.

17 Finally, the Court should takes into account that it is not just § 422.310(d)(1) that is
 18 relevant here. Section 422.310(d)(1) should be read in conjunction with § 422.504(l), *i.e.*, the
 19 regulation that requires a MA organization to provide accurate risk adjustment data to CMS. *See*
 20 42 C.F.R. § 422.504(l) (“As a condition for receiving a monthly payment under subpart G of this
 21 part, the MA organization agrees that its chief executive officer (CEO), [etc.] must request
 22 payment under the contract on a document that certifies (based on best knowledge, information,
 23 and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests.”).
 24 While § 422.504(l) requires accuracy from a MA organization, § 422.310(d)(1) essentially
 25 provides a benchmark to assess the accuracy of the information provided. Kaiser does not dispute
 26 that adherence to the ICD Guidelines facilitates the accuracy of medical information provided.
 27 The Ninth Circuit’s decision in *United States ex rel. Swoben v. United Healthcare Insurance Co.*,
 28 848 F.3d 1161 (9th Cir. 2016), is not the contrary. *See id.* at 1179 (noting that “nothing in §

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1 422.310(d)[(1)] speaks to a Medicare Advantage organization’s obligations to ensure the accuracy
2 of risk adjustment data, [and therefore] it does not modify a Medicare Advantage organization’s
3 obligations under [§] . . . 422.504(1)’’).

4 b. Materiality

5 For the reasons stated above, the Court agrees with the government that Kaiser is required
6 to comply with the ICD Guidelines, both as a matter of contract and under the applicable
7 regulations – and thus it has a plausible case of legal falsity (*i.e.*, Kaiser implicitly certified that it
8 had complied with the ICD Guidelines in making a claim for payment). Kaiser argues that, even if
9 this is true, the legal falsity claim must still be dismissed because the government has not
10 adequately alleged that the false statement regarding compliance with the ICD Guidelines was
11 material.

12 As noted above, under the FCA, “the term ‘material’ means having a natural tendency to
13 influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. §
14 3729(b)(4). The Supreme Court in turn has noted that the FCA is not

15 a vehicle for punishing garden-variety breaches of contract or
16 regulatory violations. A misrepresentation cannot be deemed
17 material merely because the Government designates compliance
18 with a particular statutory, regulatory, or contractual requirement as
19 a condition of payment. Nor is it sufficient for a finding of
materiality that the Government would have the option to decline to
pay if it knew of the defendant’s noncompliance. Materiality, in
addition, cannot be found where noncompliance is minor or
insubstantial.

20 *Escobar*, 579 U.S. at 193.

21 In the case at bar, the government has adequately alleged materiality – particularly when
22 the considerations below are taken collectively. First, as the government explains,

23 submitting accurate ICD diagnosis codes is material because CMS
24 makes risk-adjustment payments based directly on the codes
25 submitted by MAOs. . . . An ICD code that violates the ICD
Guidelines because the condition had nothing to do with a patient
visit is not an accurate ICD code

26 Opp’n at 21. Under MA, risk adjustment payments in the aggregate are obviously substantial.
27 Misrepresentations which affect those payments can undoubtedly have a substantial financial
28 effect on the MA program. Health risk assessments are a core element of the program.

1 Second, the CMS Medicare Managed Care Manual makes explicit the importance of
2 complying with the ICD Guidelines, including the ones that are the focus of the government’s
3 case. The Manual notes as follows:

4 Medicare Advantage Organizations (MAOs) . . . must . . . [e]nsure
5 the accuracy and integrity of risk adjustment data submitted to CMS.
6 All diagnosis codes submitted must be documented in the medical
7 record and must be documented as a result of a face-to-face visit.
8 The diagnosis must be coded according to [the ICD Guidelines].

9 Def.’s RJN, Ex. C (CMS Medicare Managed Care Manual, Ch. 7, § 40); *see also* U.S. Compl. ¶
10 81. And notably, Kaiser’s own internal documents (*e.g.*, its Program Advisories on risk
11 adjustment) recognized the need to comply with the ICD Guidelines, including the ones that are
12 the focus of the government’s case here. *See, e.g.*, U.S. Compl. ¶ 90 (noting that Kaiser’s 2008
13 Program Advisory specified, *inter alia*, that risk adjustment data must be obtained as a result of a
14 face-to-face visit and that the doctor must have considered or addressed the coded diagnosis
15 during the encounter); *see also Escobar*, 579 U.S. at 193 (noting that “[w]hat matters is not the
16 label the Government attaches to a requirement, but whether the defendant knowingly violated a
17 requirement that the defendant knows is material to the Government’s payment decision.”).

18 Finally, as indicated above, the magnitude of the noncompliance weighs in favor of
19 materiality, as the government has asserted that Kaiser has “reap[ed] thousands of dollars for each
20 inaccurate diagnosis code and hundreds of millions of dollars for its scheme.” Opp’n at 23; *see*
21 *also* U.S. Compl. ¶ 335 (alleging that “false claims inflated CMS’s reimbursements to the Kaiser
22 Health Plans by hundreds of millions of dollars”). *See, e.g., United States ex rel. Rose v. Stephens*
23 *Inst.*, 909 F.3d 1012, 1022 (9th Cir. 2018) (indicating that noncompliance can be deemed minor or
24 insubstantial where there is no real monetary impact – “[f]or instance, were a school to offer
25 admissions representatives cups of coffee or \$10 gift cards for recruiting higher numbers of
26 students, there would be no viable claim under the False Claims Act”).

27 5. Statute of Repose/Statute of Limitations

28 Kaiser argues that, even if the government has adequately pled FCA causes of action, those
claims should still be trimmed because part of the claims are time barred. Below is the relevant
provision from the FCA:

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- (b) A civil action under section 3730 [31 U.S.C. § 3730] may not be brought –
 - (1) more than 6 years after the date on which the violation of section 3729 [31 U.S.C. § 3729] is committed, or
 - (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
 whichever occurs last.

(c) If the Government elects to intervene and proceed with an action brought under [section] 3730(b) [31 U.S.C. § 3730(b)], the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) [31 U.S.C. § 3730(b)] to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

31 U.S.C. § 3731(b)-(c).

Kaiser contends that the provision above contains not just a statute of limitations but also a statute of repose.

Statutes of limitations and statutes of repose both are mechanisms used to limit the temporal extent or duration of liability for tortious acts. Both types of statute can operate to bar a plaintiff’s suit, and in each instance time is the controlling factor. There is considerable common ground in the policies underlying the two types of statute. But the time periods specified are measured from different points, and the statutes seek to attain different purposes and objectives. . . .

In the ordinary course, a statute of limitations creates “a time limit for suing in a civil case, based on the date when the claim accrued.” Measured by this standard, a claim accrues in a personal-injury or property-damage action “when the injury occurred or was discovered.” . . .

A statute of repose, on the other hand, puts an outer limit on the right to bring a civil action. That limit is measured not from the date on which the claim accrues but instead from the date of the last culpable act or omission of the defendant. A statute of repose “bar[s] any suit that is brought after a specified time since the

1 defendant acted (such as by designing or manufacturing a product),
 2 even if this period ends before the plaintiff has suffered a resulting
 3 injury.” The statute of repose limit is “not related to the accrual of
 4 any cause of action; the injury need not have occurred, much less
 5 have been discovered.” The repose provision is therefore equivalent
 6 to “a cutoff,” in essence an “absolute . . . bar” on a defendant’s
 7 temporal liability, C. J. S. §7, at 24.

8 *CTS Corp. v. Waldburger*, 573 U.S. 1, 8 (2014).

9 Although the Supreme Court in *CTS* underscored the distinction between a statute of
 10 limitations and a statute of repose, it also recognized that “general usage of the legal terms [statute
 11 of limitations and statute of repose] has not always been precise” – e.g., “Congress has used the
 12 term ‘statute of limitations’ when enacting statutes of repose,” and “petitioner does not point out
 13 an example in which Congress has used the term ‘statute of repose.’” *Id.* at 13-14; *see also Fed.*
 14 *Hous. Fin. Agency v. Nomura Holding Am., Inc.*, 873 F.3d 85, 113 (2d Cir. 2017) (noting that,
 15 “although Congress has indisputably created statutes of repose in the past, it ‘has never used the
 16 expression “statute of repose” in a statute codified in the United States Code”). Even after *CTS*,
 17 the Supreme Court itself has not always been precise about the use of the terms, including in a
 18 FCA case. In *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507 (2019), the
 19 Court stated as follows:

20 The False Claims Act contains two limitations periods that apply to
 21 a “civil action under section 3730” – that is, an action asserting that
 22 a person presented false claims to the United States Government.
 23 The first period requires that the action be brought within 6 years
 24 after the statutory violation occurred. The second period requires
 25 that the action be brought within 3 years after the United States
 26 official charged with the responsibility to act knew or should have
 27 known the relevant facts, but not more than 10 years after the
 28 violation. Whichever period provides the later date serves as the
limitations period.

Id. at 1510 (emphasis added).

29 In the instant case, Kaiser maintains that, although § 3731(b) of the FCA contains a statute
 30 of limitations, it also contains a statute of repose – specifically in (b)(2) – due to the following
 31 language: “but in no event more than 10 years after the date on which the violation is committed.”
 32 31 U.S.C. § 3731(b)(2).

33 Kaiser then argues that, because the government did not file its complaint until October 25,

1 2021, the statute of repose dictates that the government’s claims are valid only to the extent they
 2 are based on conduct occurring on or after October 25, 2011. Thus, according to Kaiser, the
 3 government’s attempt to implicate conduct as far back as 2009 should be rejected. *See* U.S.
 4 Compl. ¶ 1 (“Beginning sometime prior to 2009 and continuing through at least 2018, Kaiser
 5 engaged in a coordinated scheme to unlawfully obtain payments from the Medicare Part C
 6 program, also called Medicare Advantage.”).

7 Kaiser acknowledges that the FCA contains a relation back provision in § 3731(c). It also
 8 recognizes – implicitly – the government’s contention that, under § 3731(c), it can claim relation
 9 back to the *Osinek* complaint (filed in 2013) or the *Taylor* complaint (filed in 2014), and then,
 10 because *Osinek* was filed in 2013 and *Taylor* in 2014, § 3731(b)(1) would allow the government to
 11 wrap in conduct six years earlier – *i.e.*, from 2007 and 2008. But Kaiser contends that the
 12 government rely on § 3731(c) because that provision in the FCA only mentions relation back and
 13 the statute of limitations, not the statute of repose. In support of this argument, Kaiser relies on
 14 *United States v. Scan Health Plan*, No. CV 09-5013-JFW (JEMx), 2017 U.S. Dist. LEXIS 174308
 15 (C.D. Cal. Oct. 5, 2017) [hereinafter *Swoben II*]. There, the court held as follows:

16 [T]he Government[] cannot rely on the relation back doctrine
 17 contained in Section 3731(c) because Section 3731(c) is specifically
 18 limited to “statute of limitations purposes.” In fact, Congress added
 19 the relation-back provision [to the FCA] in 2009, as part of the same
 20 legislation in which it considered consolidating the separate statutes
 21 of limitations and repose into a single ten-year statute of limitations
 22 before rejecting that consolidation as insufficiently protective of
 23 defendants’ interests in repose. As one False Claims Act expert
 24 testified during the Senate’s consideration of those changes, without
 25 a repose period, the relation-back provision would have forced
 26 defendants “to defend themselves for actions that occurred 12, 15 or
 27 even 20 years ago, depending on how long a qui tam case remains
 28 under seal.”

Id. at *27-28.

24 But at least one court has expressly disagreed with the analysis in *Swoben II*. Its reasoning
 25 was that “subsection (c)’s relation-back provision does not distinguish between ‘statutes of
 26 limitation’ and the ‘statute of repose,’” and so “ the Court concludes that subsection (c) refers to
 27 the various timing restrictions contained in subsection (b), the statute of repose included.” *United*
 28 *States ex rel. Ling v. City of L.A.*, No. CV 11-974 PSG (JCx), 2018 U.S. Dist. LEXIS 136589, at

1 *70-71 (C.D. Cal. July 25, 2018).

2 Arguably, both the analysis in *Ling* and that in *Swoben II* are problematic in that they rely
 3 on terminology used in § 3731(c) but neither Congress nor the Supreme Court has been precise in
 4 their use of the term “statute of limitations” or “statute of repose.” Given the ambiguity of the
 5 terms as they appear in this statute, the more fundamental question is whether as a matter of
 6 principle it would be improper to apply relation back where there is a statute of repose (as opposed
 7 to a statute of limitations). On this question, the government correctly argues that it would not
 8 because relation back does not alter a limitations period or repose period, nor does it even toll one.
 9 Rather relation back simply pinpoints *when a claim is filed*. See Opp’n at 25. This was the basic
 10 point that the Third Circuit made when considering whether the FCA’s statute of repose prevented
 11 relation back under Federal Rule of Civil Procedure 15(c) (*i.e.*, instead of relation back under §
 12 3731(c) of the FCA): “[T]olling extends the repose period, while relation back *keeps the repose*
 13 *period intact*.” *SEPTA v. Orrstown Fin. Servs.*, 12 F.4th 337, 351 (3d Cir. 2021) (emphasis
 14 added). The Third Circuit’s analysis is convincing.

15 Accordingly, the Court reject Kaiser’s argument that the government’s claims cannot reach
 16 back to conduct from 2009 given the application of relation back.

17 6. Summary

18 For the foregoing reasons, the government’s FCA claims largely survive Kaiser’s 12(b)(6)
 19 challenge. The FCA claims are not viable only to the extent the government has argued factual
 20 falsity on a systemic basis because diagnoses were made for nonexistent conditions. The
 21 government has not pled enough to support this factual falsity claim with one exception – *i.e.*, that
 22 there was a scheme to amend patient records to add a clinically inaccurate diagnosis of cachexia.
 23 The government has leave to amend its complaint for this factual falsity theory. Any amended
 24 complaint shall be filed by December 12, 2022. Kaiser shall then have until January 3, 2023 to
 25 file a response, whether an answer or a motion.

26 C. Claims for Payment by Mistake and Unjust Enrichment

27 Aside from the FCA claims, the government has also asserted the following causes of
 28 action: payment by mistake and unjust enrichment. According to Kaiser, these are common law

1 claims that should be dismissed for two reasons: (1) the claims are “derivative of the flawed FCA
2 claims”⁹ and (2) with respect to the Health Plans (who contracted with CMS to provide the MA
3 plans), “quasi-contractual claims are unavailable” because of the express contract between the
4 Health Plans and CMS. Mot. at 24. Kaiser adds that, even as to the Permanente Medical Groups
5 (who contracted with the Health Plans to provide services to patients), “it is not clear how the
6 government could have quasi-contract claims” because the government alleges that the
7 Permanente Medical Groups “must ‘comply with’ the Health Plan Defendants’ ‘contractual
8 obligations to CMS.’” Mot. at 25.

9 The Court rejects Kaiser’s first argument because, as discussed above, the FCA claims
10 largely survive.

11 Kaiser’s second argument presents a closer call. Kaiser does have authority to support its
12 position. For example, in *United States v. First Choice Armor & Equipment*, 808 F. Supp. 2d 68,
13 (D.D.C. 2011), the district court noted as follows:

14 The defendants argue that the government cannot simultaneously
15 proceed on its FCA claims and its claims of payment by mistake and
16 unjust enrichment. Rule 8(d)(2) allows a plaintiff to plead
17 alternative theories of liability. Accordingly, “at the motion-to-
18 dismiss stage, courts in this district . . . have permitted the
19 government to proceed with claims alleging FCA violations as well
20 as claims for unjust enrichment or payment by mistake.” However,
21 “it does not appear that the D.C. Circuit has [wavered] from the rule
22 that ‘there can be no claim for unjust enrichment when an express
23 contract exists between the parties.’” Allegations in a complaint that
24 an express contract existed between the parties, therefore, preclude a
25 plaintiff from proceeding on alternative theories of FCA liability and
26 unjust enrichment or payment by mistake.

27 *Id.* at 77-78; *see also United States ex rel. Doughty v. Or. Health & Scis. Univ.*, No. 3:13-CV-
28 01306-BR, 2017 U.S. Dist. LEXIS 55083, at *18 (D. Or. Apr. 11, 2017) (“[T]he basis for
Plaintiff-Relators’ claims for payment by mistake and unjust enrichment arise from the express
contracts the government alleged in its Complaint. In fact, Defendant could only have been

⁹ In its reply, Kaiser acknowledges that a FCA claim requires a knowing false representation, while payment by mistake and unjust enrichment do not. However, it argues that, if there is no falsity, then there can be FCA claim, not a cause of action for payment by mistake or unjust enrichment.

1 enriched unjustly and payments to Defendant could only have been mistaken if the express
2 contracts did not set out specific rates and methods for charging costs. . . . The Court, therefore,
3 concludes Plaintiff-Relators have not stated claims for unjust enrichment or payment by
4 mistake.”).

5 Nevertheless, Kaiser’s position is problematic given that the government has not simply
6 alleged the violation of the CMS/Kaiser contract but also the violation of federal regulations. In
7 other words, if the Court or the trier of fact were to find that Kaiser’s failure to comply with the
8 ICD Guidelines was not a violation of the CMS/Kaiser contract, then why should the government
9 not be able to proceed with a quasi-contractual theory at that point? *Cf. United States ex rel.*
10 *Costa v. Baker & Taylor, Inc.*, No C-95-1825-VRW, 1998 U.S. Dist. LEXIS 23509, at *36 (N.D.
11 Cal. Mar. 20, 1998) (“In the present case, plaintiffs believe that their contracts with defendants are
12 valid. In the unlikely event that the court should find these contracts invalid, however, plaintiffs
13 have included claims for unjust enrichment and payment by mistake.”).

14 More important, the government persuasively argues that, even if a quasi-contract claim
15 might ordinarily be barred where an express contract exists, its claim is unique precisely because
16 the government is involved.

17 When a payment is erroneously or illegally made, as is alleged here,
18 “it is in direct violation of . . . the Constitution.” To correct for this
19 violation, the United States may exercise its “[well]-established right
20 to sue for money wrongfully or erroneously paid from the public
treasury,” *a right arising separate and apart from statute,
regulation, or contract.*

21 *Agility Public Warehousing Co. K.S.C.P. v. United States*, 969 F.3d 1355, 1365 (Fed. Cir. 2020);
22 *see also United States v. Wurts*, 303 U.S. 414, 415 (1938) (“The Government by appropriate
23 action can recover funds which its agents have wrongfully, erroneously, or illegally paid. ‘No
24 statute is necessary to authorize the United States to sue in such a case. The right to sue is
25 independent of statute,”); *id.* at 416 (“The Government’s right to recover funds, from a
26 person who received them by mistake and without right, is not barred unless Congress has ‘clearly
27 manifested its intention’ to raise a statutory barrier.”); *United States ex rel. Robinson-Hill v.*
28 *Nurses’ Registry & Home Health Corp.*, No. 5:08-145-KKC, 2015 U.S. Dist. LEXIS 68222, at *8

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1 (E.D. Ky. May 27, 2015) (“The United States’ common law claims for fraud, unjust enrichment,
2 and payment by mistake also survive Mr. House’s death. ‘The Government by appropriate action
3 can recover funds which its agents have wrongfully, erroneously, or illegally paid.’”).

4 **III. CONCLUSION**

5 For the foregoing reasons, the Court grants in part and denies in part Kaiser’s motion to
6 dismiss the government’s complaint. The Court grants the motion only to the extent that the
7 government has failed to plead a FCA claim based on a scheme by Kaiser to alter patient medical
8 records by adding clinically inaccurate diagnoses on a general or systemic basis. The government,
9 however, has adequately alleged a general scheme to add clinically inaccurate diagnoses for
10 cachexia (specifically). It has also adequately alleged a FCA violation based on Kaiser adding
11 clinically accurate diagnoses but for which no treatment was provided at the time of the doctors’
12 visits. The FCA claims are not time barred. As for the claims for payment by mistake and unjust
13 enrichment, they are allowed to proceed.

14 The government has leave to file an amended complaint by December 12, 2022. If the
15 government files an amended complaint, then Kaiser shall file a response by January 3, 2023. If
16 no amended complaint is filed by December 12, 2022, then Kaiser shall answer the original
17 complaint in intervention by January 3, 2023.

18 This order disposes of Docket No. 178.

19
20 **IT IS SO ORDERED.**

21
22 Dated: November 14, 2022

23
24 

25 EDWARD M. CHEN
26 United States District Judge
27
28